

**DETAILED ACTION**

***Response***

1. The Applicant's arguments filed 1/15/10 are convincing, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 5, 7 and 23-25 are rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 6,115,630 to Stadler et al., hereafter Stadler (who incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al., hereafter Mouchawar, who incorporates by reference U.S. Patent No. 5,628,777 to Moberg et al., hereafter Moberg), in view of U.S. Patent No. 6,480,111 to Canady et al., hereafter Canady.

Stadler discloses a method and apparatus for properly orienting monitored cardiac information relating to ischemia (abstract; column 1, lines 27-33), and then comparing the information to a threshold (S235, S236). An accelerometer is implanted at the apex of the heart. The measured endocardial acceleration signal, which is analyzed in real time, or is recorded in memory for later analysis, correlates well with periods of coronary occlusion, recognized to be

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periods of ischemia (abstract; column 5, lines 4-10; column 12, lines 31-47; column 13, lines 37-49; column 17, lines 25-28; column 28, line 62 - column 29, line 8).

As related to instant claim 7, data collected that relates to detection ischemia is stored in memory for later uplink telemetry transmission (Figure 2 – 120) and for analysis by the physician (column 12, lines 31-33; column 13, lines 8-36).

Stadler incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al. (column 28, line 63 – column 29, line 8).

Mouchawar discloses a system and method for deriving hemodynamic signals from a cardiac wall motion sensor, and integrating the signals over time to derive velocity/ speed and acceleration (abstract). The motion sensor is mounted at the distal end of an implantable lead (column. 4, lines 15-26).

As related to instant claim 7, a telemetry system (Figure 3 – 314) enables communication between the implanted device and the external programmer (column 9, lines 16-21).

Mouchawar et al. incorporate by reference U.S. Patent No. 5,628,777 to Moberg et al. (column 2, lines 48-57; column 6, lines 4-6).

Moberg discloses implantable leads that comprising accelerometer-based cardiac wall motion sensors (abstract). The electrode may be a patch electrode, an epicaridal electrode attached to the outer surface of the heart, (Figures 3-6 - 60, 160, 260, 360; column 6, lines 49-54) comprising a motion sensor (Figure 3-6 - 68, 168, 268, 368; column 7, line 30 – column 9, line 48). The patch electrode is sutured in the cardiac wall of the right and/ or left ventricular in the region selected to be monitored, or at the selected position corresponding to the area that is supplied by the selected vessel (column 8, lines 65-67; column 21, lines 18-22).

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As related to instant claims 4 and 24, the lead may also be an endocardial lead comprising a piezoelectric wall motion sensor (Figure 8 – 568; Figures 13-15 - 214; column 14, lines 10-16) and a helically-shaped tip electrode (Figure 8 - 118), the helical shape of the electrode making the electrode removable from its position without requiring surgical intervention.

As related to instant claim 5, the accelerometer-based cardiac wall motion sensors are sensitive along three perpendicular axis (column 3, lines 33-43).

As related to instant claim 7, a telemetry network (256, 258) enables communication between the implanted device and the external device (Figure 18; column 19, lines 3-10).

As discussed in the previous eleven paragraphs of this action, Stadler discloses the claimed invention except for determining a frequency distribution.

Canady teaches motion detection by determining the frequency distribution of magnetic field sensors/ accelerometer signals for the purpose of clearly detecting and classifying the signals reflecting the motion of the heart wall. It would have been obvious to one having ordinary skill in the art at the time of the invention to have determined a frequency distribution of the acceleration signals in the Sadler system in order to use a proven means of data analysis that can directly and clearly discern the relative differences in the heart motion and does not have to interpret electrical physiological responses (abstract; column 1, lines 36-60; column 3, lines 12-20, 31-46; column 7, lines 44-48).

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3. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,115,630 to Stadler et al., hereafter Stadler (who incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al., hereafter Mouchawar, who incorporates by reference U.S. Patent No. 5,628,777 to Moberg et al., hereafter Moberg), and U.S. Patent No. 6,480,111 to Canady et al., hereafter Canady in view of U.S. Patent No. 6,328,698 to Matsumoto, hereafter Matsumoto.

As discussed in paragraph 2 of this action, modified Stadler discloses the claimed invention except for the method being performed post operatively in connection with a bypass operation where the area of the heart monitored by the motion sensor is associated with a “revascularised” coronary artery.

Matsumoto teaches a diagnostic system for diagnosing cardiac disease using a three axial accelerometer for the purpose of detecting displacement of the chest wall and teaches monitoring the patient after a bypass procedure where cardiac coronary vascular flow is improved. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the three axial accelerometer for the purpose of monitoring a patient after a bypass procedure where cardiac coronary vascular flow is improved in the modified Stadler et al. system in order to provide a proven means to evaluate the effectiveness of a procedure involving a bypass, and in order to follow the patient's cardiac performance closely during the post-operative period (abstract; column 2, lines 45-50; column 3, lines 45-48, 63-64; column 9, lines 52-64).

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,115,630 to Stadler et al., hereafter Stadler (who incorporates by reference U.S. Patent No.

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5,480,412 to Mouchawar et al., hereafter Mouchawar, who incorporates by reference U.S. Patent No. 5,628,777 to Moberg et al., hereafter Moberg), and U.S. Patent No. 6480111 to Canady et al., hereafter Canady in view of U.S. Patent No. 6,275,724 to Dickinson et al., hereafter Dickinson.

As discussed in paragraph 2 of this action, modified Stadler discloses the claimed invention except for the motion sensor comprising a gyroscope.

Dickinson teaches cardiac monitoring using a three-axis solid state gyroscope or a three-axis accelerometer for the purpose of monitoring the position and location of the catheter. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a three-axis solid state gyroscope in the modified Stadler system in order to provide a known alternative sensor to the accelerometer presently used in the system so the system user has the option to choose the most appropriate motion sensor for the application, and in order that the invention disclosed by Stadler identify additional applications in cardiac medicine (column 1, lines 4-14; column 5, lines 51-54; column 6, lines 2-4; column 9, lines 52-61).

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,115,630 to Stadler et al., hereafter Stadler (who incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al., hereafter Mouchawar, who incorporates by reference U.S. Patent No. 5,628,777 to Moberg et al., hereafter Moberg), and U.S. Patent No. 6480111 to Canady et al., hereafter Canady, in view of U.S. Patent No. 6,328,698 to Hess, hereafter Hess.

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Stadler teaches an accelerometer implanted at the apex of the heart. The measured endocardial acceleration signal correlate well with periods of coronary occlusion recognized to be period of ischemia (column 28, line 62 - column 29, line 8).

As discussed in the preceding paragraph and in paragraph 2 of this action, modified Stadler discloses the claimed invention except for the motion sensor being incorporated in a temporary pacemaker electrode.

Hess teaches interim pacing using a temporary pacemaker electrode for the purpose of providing stimulus to the heart during medical procedure such as replacement of a cardiac pacemaker. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a temporary lead including a motion sensor in the modified Stadler system in order to effectively monitor the patient after a procedure and to be able to rapidly respond to any cardiac pacing or ischemia issues that might arises (column 1, lines 37-44).

### ***Statutory Basis***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Carl. H. Layno can be

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reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM – 5PM EST; Tuesday, Thursday 9AM–3PM and 9PM–11PM EST.

The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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